

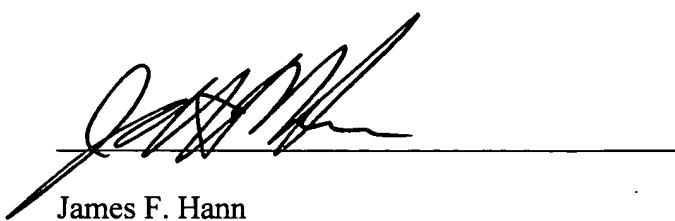
REMARKS

Claim 1 is similar to but broader than claim 1 of U.S. Patent No. 6,270,464.

If the Examiner believes a telephone conversation would aid the prosecution of this case in any way, please call James F. Hann, Reg. No. 29,719, an attorney a record in this case, at (650) 712-0340.

Respectfully submitted,

Dated: 20 Dec 2001



James F. Hann

Reg. No. 29, 719

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APPENDIX

The following is a marked up copy of the amended paragraph at lines 4-9 from page 1 of the specification.

This application is a continuation of application No. 09/900,801 filed 6 July 2001, which application is a continuation of application No. 09/366,360 filed June 18, 1999, now U.S. Patent No. 6,270,464 issued August 7, 2001, which application claims the benefit of the following Provisional patent applications. Biopsy Localization Device, Application No. 60/090,243, filed June 22, 1998; Biopsy Localization and Hemostasis Device, Application No. 60/092,734, filed July 14, 1998; Device and Method of Biopsy Localization and Hemostasis, Application No. 60/114,863, filed January 6, 1999; and Device and Method of Biopsy Localization, Hemostasis & Cancer Therapy, Application No. 60/117,421, filed January [25] 27, 1999.

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PROVISIONAL
APPLICATION
NUMBER

60/092,734

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PATENT APPLICATION



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Box Provisional Patent Application
Assistant Commissioner for Patents
Washington, District of Columbia 20231

Mailed 1998 July 14



Sir:

Please file the enclosed Provisional Patent Application (PPA) papers listed below under 37 C.F.R. § 1.53(b)(2).

Each of the undersigned understands:

- A. This PPA is not a substitute for a Regular Patent Application (RPA), cannot be converted to an RPA, cannot get into interference with an RPA of another person, cannot be amended, will not be published, cannot claim any foreign priority, and will not mature into a patent;
- B. If an RPA referring to this PPA is not filed within one year of the filing date of this PPA, this PPA will be worthless and will be destroyed;
- C. Any desired foreign Convention applications (including PCT applications) based upon this PPA must be filed within one year of the filing date of this PPA;
- D. This PPA must contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. 35 U.S.C. § 112, ¶ 1. Otherwise this PPA will be worthless.
- E. Any RPA will be entitled to claim the benefit of this PPA only if such RPA names at least one inventor of this PPA and this PPA discloses such inventor's invention, as claimed in at least one claim of the RPA, in the manner provided in Item D above.

Tentative Applicant #1, Name: RICHARD E. FULTON

Tentative Applicant #2, Name: N/A

Title: Biopsy Localization AND HEMOSTATIS DEVICE

(x) Specification, sheets: 14 () Drawing(s), sheets: 4

(Small Entity Declaration(s), number: 1)

(x) Check for \$ 75.00 for (small entity) (large entity filing fee)

(x) Return Receipt Postcard Addressed to Applicant #1.

Very respectfully,

Richard E. Fulton

Applicant #1 Signature

N/A

Applicant #2 Signature

1557 Wellington Ave

Address (Send Correspondence Here)

Address

GRAND JUNCTION, CO 81501

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I hereby certify that this paper or fee is being deposited with the United States Postal Service using "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to "Box Provisional Patent Application, Assistant Commissioner for Patents, Washington, DC 20231."

Signed: Richard E. Fulton

Inventor

14JULY98REF

Provisional Patent Application of

Richard Eustis Fulton III

for

BIOPSY LOCALIZATION AND HEMOSTASIS DEVICE

FIELD OF THE INVENTION

The present invention relates to a medical device utilized during and subsequent to needle biopsies and localizations of breast lesions and other soft tissue lesions. More particularly, the present invention relates to a medical device which is deployed at the time of a needle biopsy and marks the site of biopsy so that the site can be located subsequently by palpation or other means to guide surgical resection or other intervention. The device may also be used primarily to localize a lesion prior to any biopsy or excision. A secondary purpose of the device is hemostasis.

BACKGROUND OF THE INVENTION

Breast cancer is the most frequently diagnosed malignancy of women in the United States, excluding skin cancers, and accounts for nearly one in

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three newly diagnosed cancers. The American Cancer Society estimates that 190,000 new cases of breast cancer will be diagnosed this year and that 45,000 women will die from breast cancer. It is the second leading cause of death from cancer.

Since there is no known method or potential strategy to prevent breast cancer, the primary disease control strategy has been, and will continue to be, early detection, followed by appropriate treatment. Early detection by screening mammography in asymptomatic women is generally accepted as a way to reduce breast cancer mortality by at least 20-30%. A recently observed decline in the mortality rate of breast cancer can be traced to a rapid growth in the number of women undergoing screening mammography in the past decade. Mammography is unrivaled as the single most important method of detecting breast cancer in its earliest stages when it is most curable. While mammography is very sensitive, it lacks specificity. This means that many benign or indeterminant lesions found during mammography must undergo biopsy to ascertain the true nature of the lesion. In fact, only 15-35% of all breast biopsies reveal malignancy. It is generally accepted that approximately 80% of all breast biopsies are done for benign disease.

In the past, most biopsies were performed by surgically excising the lesion or suspicious area. However, an increasing number of biopsies for nonpalpable lesions found during mammography are being performed utilizing the less invasive and less expensive image directed large core needle techniques. There were approximately one million breast biopsies done in the United States in 1996, and approximately 400,000 were done with large core needles. Of these, approximately 100,000 were performed with

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ultrasound guidance and 300,000 were performed with stereotactic or x-ray guidance. The remainder were performed with fine needle aspiration, surgical excision, and other techniques. The present invention addresses primarily the large core needle biopsies done with ultrasound or stereotactic guidance for nonpalpable breast abnormalities.

Breast biopsies are generated because of a palpable lump or because of a nonpalpable mass or calcifications found on mammography or on an ultrasound examination. Because of the low specificity of mammography, biopsies are needed to determine if masses, calcifications, or other structures present on mammograms are benign or malignant. Biopsy of nonpalpable structures is generally accomplished in one of three manners, including surgical excision, stereotactic needle biopsy, or ultrasound needle biopsy.

Surgical excision of nonpalpable structures must be preceded by a procedure of needle localization to guide the surgeon to the appropriate location and to minimize the amount of tissue removed. A needle is placed into the breast by a radiologist and mammographic views document its placement adjacent to the suspicious area. The patient is then transported to the operating room or suite and the surgeon removes the tissue around the tip of the needle. This tissue may need to be x-rayed to determine that the suspicious area had been removed. The wound is closed and sutured and the biopsy specimen forwarded for subsequent pathologic examination. This technique of needle localization of the tumor or area in question followed by surgical excision is expensive, very invasive, potentially disfiguring, involves two procedures (needle localization and surgery), and may cause irregularities on subsequent mammograms.

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Stereotactic and ultrasound guided needle breast biopsies have emerged as alternatives to surgical excisional biopsies. Typically, the biopsies are performed with 14 gauge or larger needles and cores of tissue are taken from the suspicious area without the need for surgery. With most biopsy needles, there is an inner and outer sleeve. The tissue is retrieved through the outer sleeve usually. This coaxial design will allow a substance to be injected or inserted into the biopsy site as will be described later.

In the case of stereotactic biopsy, the suspicious area is imaged by x-rays from two different angles. A computer determines the exact location of the suspicious area within the breast and sets coordinates which are manually or automatically used to position the needle. The needle is advanced through the skin and into the breast to the specified depth and additional x-ray images are done to document the proper placement of the needle tip. Core sampling is then performed through the needle. Specimen radiographs may be done to document the presence of the suspicious area within the core samples. The patient is bandaged and the material forwarded for pathological examination.

Ultrasound guided biopsies are done in a real time manner. The lesion is visualized while scanning and the needle is advanced through the skin and into the lesion during the scanning process. The needle can be observed traversing the lesion. After core samples are taken, the patient is bandaged and the specimen forwarded for pathological examination.

Stereotactic and ultrasound guided needle biopsies enjoy obvious advantages over surgical excision in that the procedures are much less invasive and much less costly, and are easier to perform and do not cause any scar or disfiguration. The accuracy is essentially the same as surgical excision. These image guided biopsy techniques obviate a need for a surgical

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procedure in most all cases, including the ones in which the pathological diagnosis is benign or malignant.

In the twenty per cent of patients with a malignant diagnosis, a second procedure is required irrespective of the type of initial procedure, i.e., surgical excision or image guided biopsy. While a mastectomy could be performed, typically a wide excision of the previously biopsied area is performed to remove any remaining tumor and some normal tissue around the margins of the tumor. Locating the previously biopsied area after surgical excision is usually not a problem because of the deformity caused by the surgery. However, if the biopsy had been done with an image directed needle technique, locating the previously biopsied area can be problematic. It is possible that the original lesion had been so small that no trace can be found with mammography, and therefore localizing the lesion for the subsequent wide excision is difficult if not impossible. The potential of removing all of the calcifications during the initial biopsy procedure and not being able to guide the surgeon back to the abnormal area is disconcerting and not optimal health care, for obvious reasons. This predicament has been addressed in the past by intentionally leaving some of the suspicious calcifications or tissue in the breast when performing the initial image directed biopsy. The obvious disadvantage of this maneuver is the potential to inadequately sample the lesion or suspicious area. Even if some of the area is left as a future landmark, a needle localization procedure is required to guide the surgeon to the correct site. There is so little tissue damage from the needle biopsies that the surgeon is not able to visually identify the correct site.

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A small metallic surgical clip, which can be deployed through a biopsy needle, has recently been developed. It is deployed through a large needle onto the wall of the tiny cavity created by the needle biopsy to guide future surgery in case the diagnosis is malignant. While effective, it is expensive and requires a subsequent needle localization with mammography prior to wide excision in those cases which are malignant. Moreover, this permanent and expensive clip is deployed unnecessarily in the 80% of women with benign diagnoses. Since the pathological diagnosis is unknown at the time of the needle biopsy, the clip cannot be utilized only in those cases which will subsequently prove to be malignant.

Thus, it is the object of the present invention to provide a simple, inexpensive device which is intended to be injected or inserted into the needle biopsy site at the termination of the procedure and which will serve as a temporary marker for subsequent surgery, and, in most cases, obviate the need for the needle localization procedure. The device would allow the surgeon to visually and tactiley locate the previously biopsied site. It is also an object of the present invention that the device be biodegradeable and resorbable, allowing the device to gradually vanish in women with benign diagnoses, obviating the unneeded permanent metallic marker in the great majority of women undergoing breast biopsies.

SUMMARY OF THE INVENTION

The subject invention relates to a medical device utilized in breast biopsies, and more particularly, breast biopsies performed utilizing image guided needle techniques. The device may be a resorbable, biodegradeable

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substance which is injected or inserted into the breast near the termination of a stereotactic or ultrasound guided large core needle biopsy. Preferentially, it is a substance which may possess or develop a consistency, after it is placed into the breast tissue, which is firm enough to be palpated by the surgeon. The device may maintain the original size, shape, and consistency once it is inserted into the body. However, the consistency of the device may be different in the non deployed state than in the deployed state, i.e., it may be less viscous or less firm in the non deployed state allowing it to be injected through the needle, whereas it may be firm or even rigid after deployment allowing it to be felt or palpated by the surgeon. Alternatively, the device may be formed with a substance which is palpable as a result of expansion, once it is within the soft tissues of the body, by absorbing body fluids or injected fluids. Also, the device may be constructed so that it expands mechanically by rotation, contraction, etc. Since the site of the previous needle biopsy could be easily located by the surgeon if the device marking the site was palpable, the needle localization procedure would not be needed. Therefore, two important components of the device are bioresorbability and a consistency which may be different in deployed and non deployed states.

The device may be constructed from one or more of the many known bioresorbable materials, many sanctioned for use in humans. These include polylactic and polyglycolic acids, polyorthoesters, resorbable silicones and urethanes, lipids, collagens, polysaccharides, starches, ceramics, polyamino acids, proteins, hydrogels and other gels, gelatins, polymers, cellulose, and others.

It is possible to change the consistency or size of materials by any one of several means including hydration or desiccation, changes in temperature,

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chemical or physical reaction with another material, additives, enzymatic reactions, ionization, electrical charges, adsorption, absorption, and other means. The device may employ one or more of these techniques or measures to change the consistency and/or size of the device from the non deployed to the deployed state.

Because some materials may react with blood or other fluids before being completely deployed, a thin coating of a second material may be needed to permit the device to be completely deployed. It is anticipated that the second material would be rather quickly biodegradeable, which would allow the first material to expand or react with body fluids soon after deployment.

It may be advantageous to enhance the visual detectability of the device by coloring it or causing it to contain a bioresorbable color such as methylene blue or other dye. This could be accomplished by one of several known methods. Furthermore, it may be desirable, in the case of deeply located lesions or large breasts, to locate the device by means other than palpation, i.e., either ultrasound or mammography. In the case of ultrasound, most any material would have reflective properties different than the surrounding breast tissue and be detectable. For the device to be detected by mammography, it would have to be radiopaque and probably contain iodine. Since one of the objects of the device is to avoid the mammographic needle localization, this feature may not be necessary.

Because the device is bioresorbable and biodegradable, the device will be of obvious advantage to those patients with benign diagnoses. However, the device must not be resorbed so quickly that it is not palpable at the time of surgical wide excision in the case of a malignant diagnosis. Typically, the

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pathologic diagnosis is available within 24-48 hours after the biopsy. The patient is then informed of the results, and if malignant, arrangements are made for surgical consultation. The patient usually is seen by the surgeon with a week and the surgery is completed within the next week. Therefore, the device must not be significantly resorbed for at least two weeks after it is deployed or implanted within the breast. There is a relative dilemma in that the device must be resorbed quickly enough to cause no discomfort or concern on the part of the patient with a benign diagnosis, but must not be resorbed until the patient with the malignant diagnosis has the necessary wide excisional surgery.

Another feature of the device is that it would provide hemostasis and lessen the bleeding and swelling within and about the biopsy site. This may be accomplished by physical or chemical means, i.e., the device may swell so that it essentially fills the biopsy cavity or that the device has a chemical reaction with blood or blood products to effect blood clotting, respectively. Other means of local hemostasis are also possible.

As well, the device may be used for hemostasis after any needle puncture or procedure for biopsy, drainage, access, or other intervention into a deep or superficial organ. There is the risk of the needle utilized for the intervention to pierce a blood vessel and cause bleeding from the needle tract through the tissues or organs or within the biopsy or accessed site. With larger needle sizes, the bleeding can be problematic, and just the threat of potential bleeding may cause a needed biopsy to be deferred or not performed. Moreover, the device may have special applicability in those patients with prolonged bleeding times, on anticoagulants, and those with a high risk of a bleeding complication.

OPERATION OF THE INVENTION

The device of the present invention is designed to be utilized during image guided breast biopsies with a large core biopsy needle. At or near the termination of the procedure, after the biopsy specimen has been retrieved, the device will be inserted through the biopsy needle and deployed within the recently biopsy site. This may be done by injecting, in the case of a liquid or semisolid material, or by inserting the device and pushing it through the needle, in the case of a more solid structure. When using a rotational vacuum assisted biopsy probe, the device would be inserted through the specimen collection chamber and through the outer needle sleeve. It would be exit the needle through the sampling notch located near the needle tip, and be deposited within the small cavity created by the recent biopsy. In the case of a TruCut type biopsy needle, the device would be inserted through the outer sleeve and out the tip into the biopsy cavity. The needle utilized for the biopsy procedure may be used or a separate needle or delivery device may be used. After the device is deposited, the needle or delivery device is removed, and the breast is compressed manually.

If surgical excision is subsequently needed in the advent of a malignant diagnosis, the biopsy site is located by palpating the device manually in most cases. This palpation may be done from externally, or from within the surgical wound, as the general location of the lesion will be known from the previous image directed biopsy and the preceding mammograms or ultrasound. In rare cases, it may be necessary to localize the device prior to the excisional surgery with image guidance, preferably ultrasound.

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Alternatively, the device may be used instead of a needle localization to primarily localize a non palpable lesion.

A secondary benefit of the device would be to cause hemostasis.

Alternatively, the device may be used primarily to achieve hemostasis by inserting or injecting the device through an existing biopsy needle, a guide needle, or a needle provided for the task. The needle tract and/or the tissue biopsied, accessed, or intervened may be so treated. In these instances, the feature of marking of the tissue for future intervention may not apply as the only purpose of the device would be to cause hemostasis.

DESCRIPTION OF THE INVENTION

The subject medical device may be made of a substance which is bioresorbable and is of a consistency or size which can be palpated days to weeks after it is deployed within the soft tissues of the body. The size or consistency may be different in the deployed and non deployed state. It may be injectable or implantable through a needle or other delivery device.

A preferred bioresorbable substance may be bovine collagen, which may be shaped into a small cylinder and inserted through a needle into the biopsy site where blood and other body fluids will cause it to swell and enlarge to a size which cause it to be palpable. It would remain palpable for several weeks and then be resorbed, if not removed surgically in the interim.

In the case that a marker is not needed for future localization, the device may be used for hemostasis by inserting the device through an existing or special needle into the site biopsied or accessed and into the needle tract to prevent bleeding from these needle interventions. This is especially valuable

within the liver, kidney, spleen, and vascular tumors and when a vascular structure is inadvertently entered with the needle.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an illustration of a stereotactic biopsy table and device, with the patient positioned, and the breast compressed for a biopsy

FIG. 2 is an illustration of a rotational vacuum assisted biopsy needle

FIG. 3 is an illustration of a needle within the breast prior to the biopsy or removal of a cluster of microcalcifications.

FIG. 4 is an illustration of the needle within the breast after removal of the calcifications.

FIG. 5 is an illustration of the subject device, represented by a cylinder of bovine collagen, being inserted into the needle.

FIG. 6 is an illustration of the subject device being deployed through the needle into the biopsy site.

FIG. 7 is an illustration of the device, enlarged because of the absorption of blood and other fluids, within the biopsy site.

FIG. 8 is an illustration of the device being palpated to localize the previously biopsied site.

While a preferred embodiment of the present invention has been described in detail, it is apparent that modifications or adaptations of that embodiment will occur to those skilled in the art. It is to be expressly understood, however, that such modifications and adaptations are within the scope of the present invention.

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What is claimed is:

1. An improved medical device which, during the course of an image directed biopsy, marks the site of the biopsy for future intervention.
2. The device of Claim 1 which, when deployed in the biopsy site, is palpable.
3. The device of Claim 1 which is bioresorbable, containing one or more biodegradeable compounds.
4. The device of Claim 1 which is injectable.
5. The device of Claim 1 which is inserted into the body.
6. The device of Claim 1 which has, in its undeployed state, a shape which is different than its deployed state.
7. The device of Claim 1 which has, in its undeployed state, a consistency which is different than its deployed state.
8. The device of Claim 1 which has, in its undeployed state, a size which is different than its deployed state.
9. The device of Claim 1 which is visible by ultrasound when implanted in soft tissue.
10. The device of Claim 1 which is visible by x-rays when implanted in soft tissue.
11. The device of claim 1 which contains a dye or coloring agent to assist in visual localization.
12. The device of Claim 1 which contains a biodegradeable coating.
13. The device of Claim 1 which is made of bovine collagen.
14. The device of Claim 1 which is made of other collagen.

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15. The device of Claim 1 which enlarges once it is inserted or injected into the body.
16. The device of Claim 1 which causes hemostasis within the biopsied tissue.
17. The device of Claim 1 which causes hemostasis within the breast.
18. An improved medical device, which during or after a needle type intervention or puncture, is utilized to cause hemostasis.
19. The device of Claim 18 which is utilized during or after a needle type intervention to cause hemostasis primarily within the needle tract.
20. The device of Claim 18 which causes hemostasis within a biopsy site.
21. The device of Claim 1 which is inserted through an existing biopsy needle.
22. The device of Claim 18 which is inserted through and existing biopsy needle, needle guide, or other needle or cannula.

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In the United States Patent and Trademark Office

First/Sole Applicant: Richard E. Fulton
Joint/Second Applicant: N/A
Title: Biopsy Localization and Hemostasis Device

Small Entity Declaration—Independent Inventor(s)

As a below-named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35 United States Code, to the Patent and Trademark Office with regard to my above-identified invention described in the specification filed herewith. I have not assigned, granted, conveyed, or licensed—and am under no obligation under any contract or law to assign, grant, convey, or license—any rights in the invention to either (a) any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or (b) any concern which would not qualify as either (i) a small business concern under 37 CFR 1.9(d) or (ii) a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization to which I have assigned, granted, conveyed, or licensed—or am under an obligation under contract or law to assign, grant, convey, or license—any rights in the invention is listed below:

There is no such person, concern, or organization.

Any applicable person, concern, or organization is listed below:

Full Name: N/A

I acknowledge a duty to file, in the above application for patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate (37 CFR 1.28(h)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Signature of Sole/First Inventor

Richard E. Factor

Print Name of Sole/First Inventor

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Date or Signature

Signature of Joint/Second/Inventor: N/A

Print Name of Joint/Second Inventor:

Date of Signature

*Note: A separate Small Entity Statement is required from any listed entity.

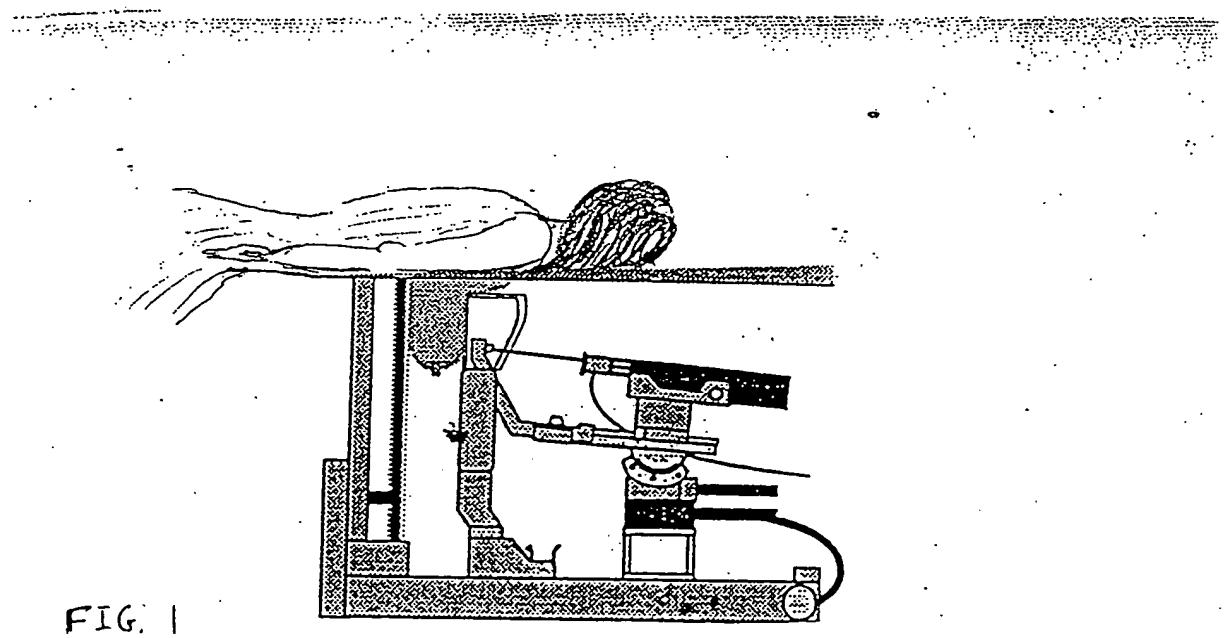
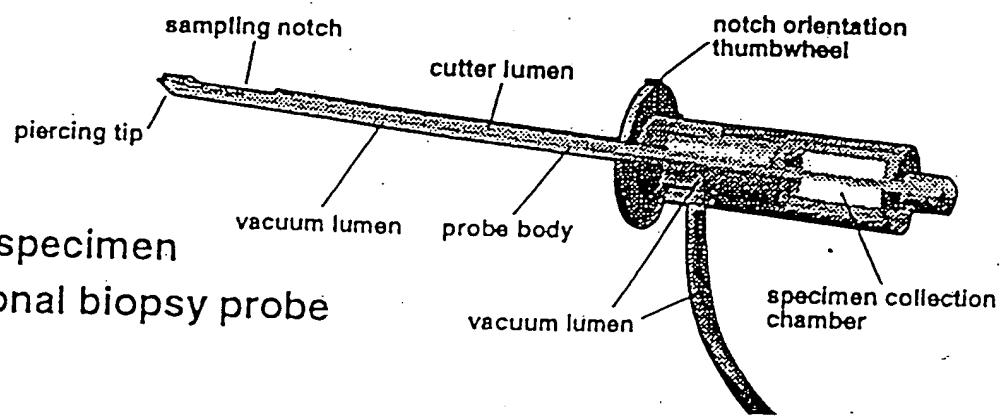


FIG. 1

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large specimen
rotational biopsy probe

FIG. 2

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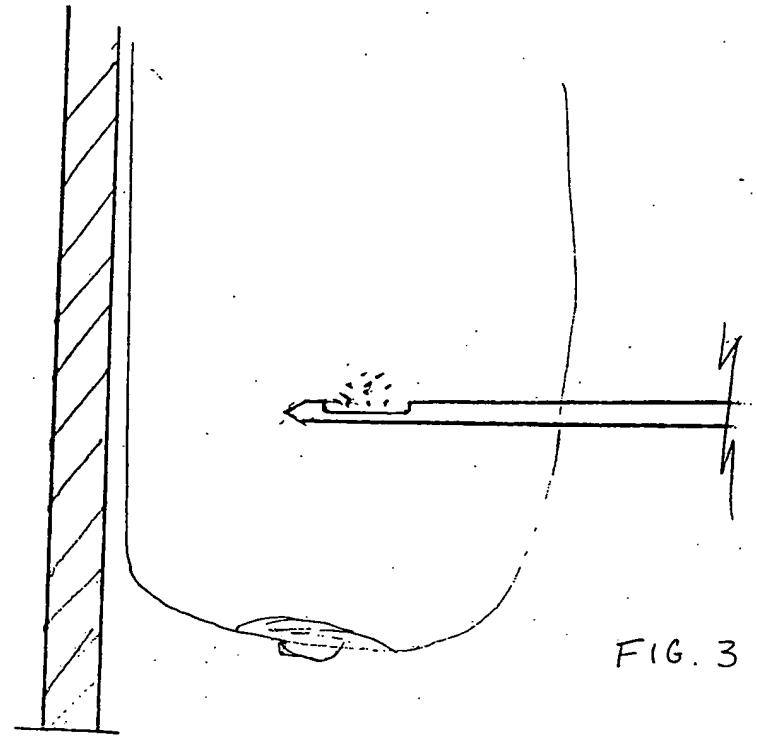


FIG. 3

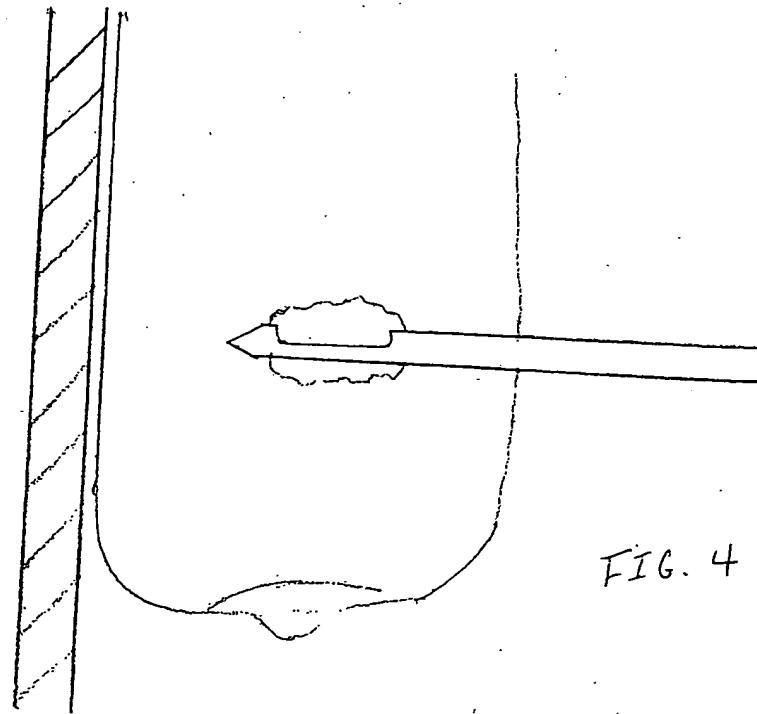


FIG. 4

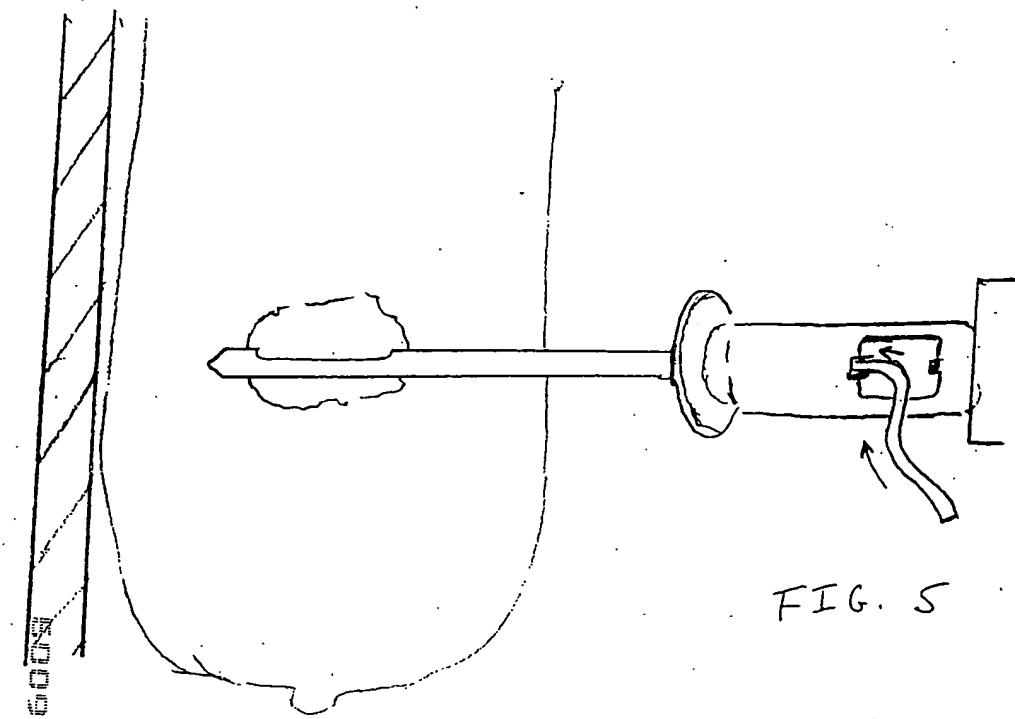


FIG. 5

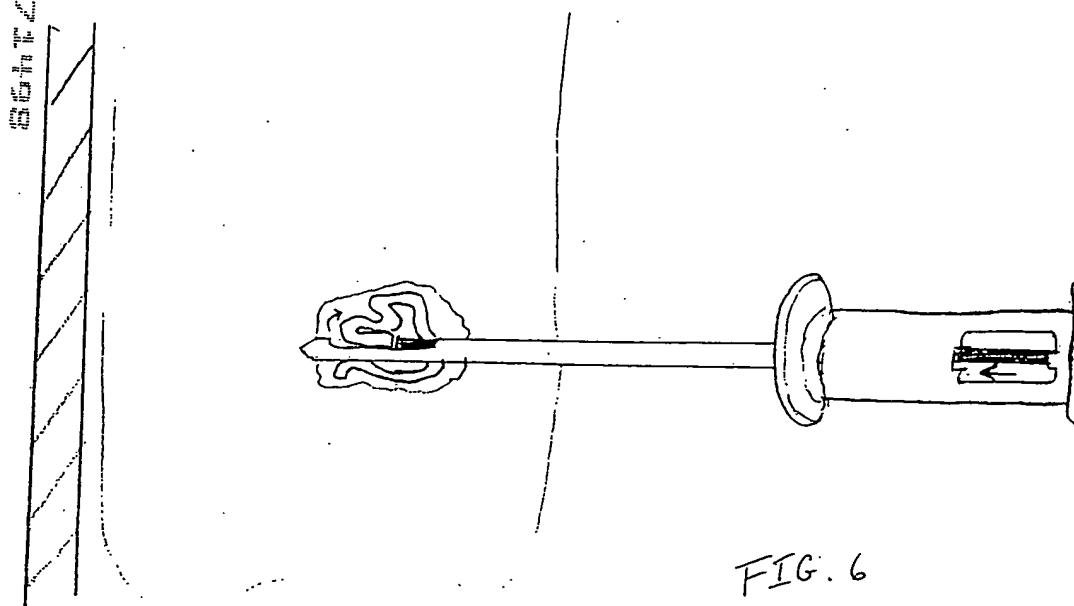


FIG. 6

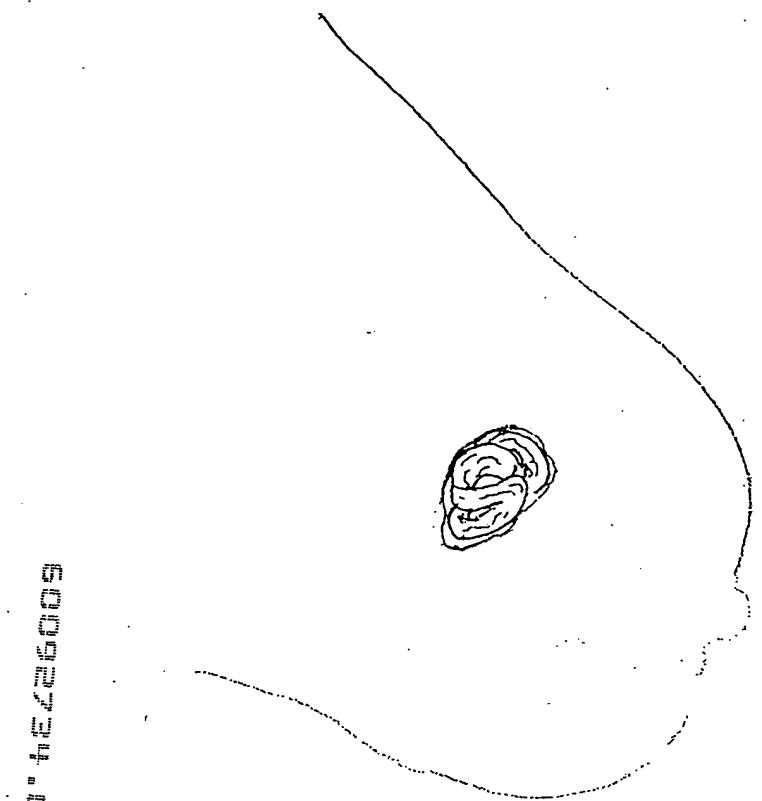


FIG. 7

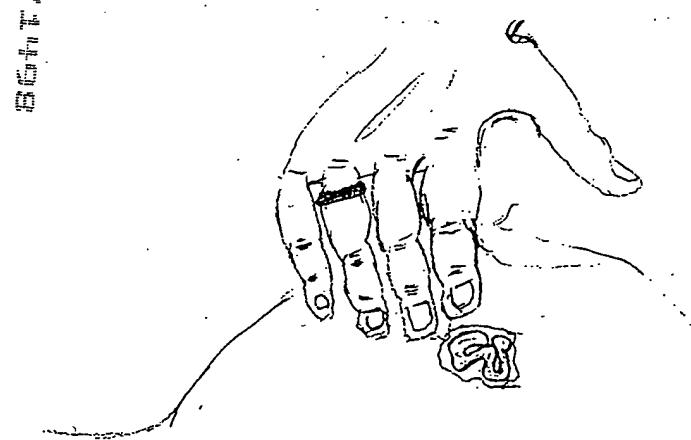


FIG. 8

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REQUEST FOR ACCESS OF ABANDONED APPLICATION UNDER 37 CFR 1.14(a)

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Group Art Unit	Examiner		

Paper No. *H2*Assistant Commissioner for Patents
Washington, DC 20231

I hereby request access under 37 CFR 1.14(a)(3)(iv) to the application file record of the above-identified ABANDONED application, which is: (CHECK ONE)

(A) referred to in United States Patent Number *6,270,464 B1*, column _____.

(B) referred to in an application that is open to public inspection as set forth in 37 CFR 1.11, i.e., Application No. _____, filed _____, on page _____ of paper number _____.

(C) an application that claims the benefit of the filing date of an application that is open to public inspection, i.e., Application No. _____ filed _____ or

(D) an application in which the applicant has filed an authorization to lay open the complete application to the public.

Please direct any correspondence concerning this request to the following address:

K. Quraishi *11-27-01*
Signature Date

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(12) United States Patent
Fulton, III et al.

(10) Patent No.: US 6,270,464 B1
(45) Date of Patent: Aug. 7, 2001

(54) BIOPSY LOCALIZATION METHOD AND DEVICE

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(73) Assignee: Artemis Medical, Inc., Hayward, CA (US)

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(58) Field of Search 600/562, 565, 600/567

(56) References Cited

U.S. PATENT DOCUMENTS

4,248,214	2/1981	Hannah et al.	128/7
4,541,438	9/1985	Parker et al.	128/664
4,592,356	6/1986	Gutierrez	128/339
4,774,948	10/1988	Markham	128/329
4,799,495	1/1989	Hawkins et al.	128/754
4,813,422	3/1989	Fisher et al.	128/634
4,817,622	4/1989	Pennypacker et al.	128/664
4,852,568	8/1989	Kensey	128/325
4,966,583	10/1990	Debbas	604/98
4,986,279	1/1991	O'Neill	128/754

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

894 503 A2 3/1999 (EP).
WO 00/38579 7/2000 (WO).

OTHER PUBLICATIONS

Hussman et al., "Optical Breast Lesion Localization Fiber: Preclinical Testing of a New Device," *Radiology*, 200:865-866 (Sep. 1996).

Hussman et al., "MR Mammographic Localization Work in Progress," *Radiology*, 189:915-917 (1993). "Surgical Treatment of Breast Disease, Making the Diagnosis of Breast Cancer: Non-Palpable Breast Masses," [BreastDoctor.com, http://www.breastdoctor.com/breast/surgery/biopsy.htm](http://www.breastdoctor.com/breast/surgery/biopsy.htm).

"Surgical Treatment of Breast Disease: What's New? Diagnosing Breast Cancer: The ABBI Breast Biopsy System," [BreastDoctor.com, http://breastdoctor.com/breast/surgery/abbi.htm](http://breastdoctor.com/breast/surgery/abbi.htm).

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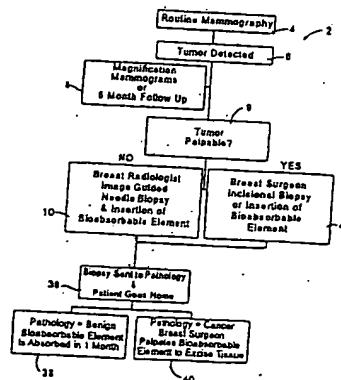
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(57) ABSTRACT

A biopsy localization device made according to the invention includes a bioabsorbable element (34), such as a dehydrated collagen plug, delivered in a pre-delivery state to a soft tissue biopsy site (18) of a patient by an element delivery device (32). The bioabsorbable element preferably swells to fill the biopsied open region (26) and preferably is palpably harder than the surrounding soft tissue at the biopsy site. The bioabsorbable element permits the biopsy site to be relocated by palpation to eliminate the need to use metallic clips during biopsies and often eliminates the need for a return to the radiologist for pre-operative localization. In addition, the bioabsorbable element can be used as a therapeutic tool for treatment of the diseased lesion and for hemostasis.

57 Claims, 3 Drawing Sheets



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60/092,734 PROVISIONAL	07/14/98		0000	

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CONTINUING DOMESTIC DATA***
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371 (NAT'L STAGE) DATA***
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FOREIGN APPLICATIONS***
VERIFIED

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Foreign Priority claimed 35 USC 119 (e-d) conditions met	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Met after Allowance	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
Verified and Acknowledged Examiner's Initials _____ Initials _____		CO	4		

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TITLE

BIOPSY LOCALIZATION AND HEMOSTASIS DEVICE

FILING FEE
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FEES: Authority has been given in Paper
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- 1.17 Fees (Processing Ext. of time)
- 1.18 Fees (Issue)
- Other _____
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